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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,949	08/09/2001	Jan Zavada	D-0021.5C-1	9458

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LEONA L. LAUDER
235 MONTGOMERY STREET, SUITE 1026
SAN FRANCISCO, CA 94104-0332

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HC

Office Action Summary	Application No.	Applicant(s)	
	09/807,949	ZAVADA ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-39,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,32,34,37-39,41 and 42* is/are rejected.

7)☒ Claim(s) *33,35 and 36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.a.D

DETAILED ACTION

Re: Zavada *et al*

1. The amendment filed 6/13/2005 is acknowledged and entered into the record. Accordingly, claims 1-30, 40, and 43-44 are canceled without prejudice or disclaimer.

2. Claims 31-39, 41-42 are pending and examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 31-32,34,37-39, and 41 are under 35 USC § 102(b) as being anticipated by Zavada *et al* (Int. J. Oncology 1997; 10:857-863) is maintained for the reasons of record. Applicant argues that the cited reference does not anticipate the instant invention. Specifically applicant argues that the cited reference does not:

i) teach each and every limitation of the claimed invention;

ii) enable how to identify the cell adhesion site of the "native" MN protein;

iii) enable how to "correctly" identify molecules that bind to the cell adhesion site of native MN protein; and

iv) enable how to "correctly" identify molecules the inhibit the binding of cells to the cell adhesion site of native MN protein.

Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

With regard to point **i)** applicant contends that the MN protein as taught in Zavada *et al* (1997) is not the same as that claimed in the instant invention, specifically because the MN protein of as taught by Zavada *et al* (1997) is not SEQ ID No: 1, but is rather a fusion protein (a GST-MN fusion protein). However, the claim as interpreted does not preclude a MN protein that comprises a fusion protein because the claim as written indicates that the MN protein only be encoded by a nucleotide sequence of SEQ ID No: 1. The sequence, as taught by Zavada *et al* (1997) is encoded by a sequence of SEQ ID No: 1. The limitation of "whose nucleotide sequence is selected from" is open language and thus reads on a fusion protein comprising SEQ ID No: 1. There is no limitation in the claim that indicates that a fusion protein (i.e. a GST) cannot be a part of the MN protein as taught by Zavada *et al*. Moreover, the limitations of groups "ii" and "iii" do not adequately define sequences by structure or activity and therefore the sequence as disclosed by Zavada *et al* meets the limitation of the claimed invention. Specifically, the sequences as claimed in groups "ii" and "iii" are open for interpretation and therefore a fusion protein comprising the MN protein encoded by SEQ ID No: 1 would fulfill the limitations as set forth in the claimed invention.

With regard to points **ii), iii)** and **iv)** applicant contends that at the time Zavada *et al* (1997) was published, the cell binding site of the MN protein was not known. Specifically, applicant contends that Zavada *et al* (1997) taught that an Mab75 bound to a PG domain of the MN protein and therefore not within the cell binding domain of the MN protein as claimed. Moreover, applicant also argues that Zavada *et al* (1997) used the adhesion assay to determine if the MN protein was a CAM and therefore an entirely

different assay from the claimed assay. However, as indicated in the last office action, the limitation of the claimed invention have been meet because one of ordinary skill would have been able to identify a compound (i.e. an Mab75 antibody) that does not inhibit the adhesion of cells to the MN protein. Applicant's arguments concerning the lack of enabling disclosure is immaterial to this case because the claims as currently written are fulfilled by the prior art. Moreover, [w]hen the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). In the instant case, applicant has not provided any objective evidence would lead one of skill in the art to presume that the reference is in fact not enabling.

Therefore, the rejection under 35 USC 102(b) as being anticipated is maintained for the reasons of record.

Claim Rejections Withdrawn - 35 USC § 112, 1st paragraph

5. The rejection of claims 31-39,41 and 42 under 35 USC § 112, 1st paragraph as lacking an enabling disclosure is withdrawn in view of the persuasive arguments set forth by the applicant in the paper filed on 6/13/2005.

Claim Rejections Maintained - 35 USC § 103

6. The rejection of claims 31-32,34,37-39, and 41-42 under 35 USC § 103(a) as being obvious over Zavada *et al* is maintained for the reasons of record. Applicant

argues that the instant invention would not have been obvious for essentially the same reasons set forth in the arguments for the 102(b) rejection, *supra*. Specifically, applicant argues that one of ordinary skill in the art would not find motivation to use human cells because the cell lines used (i.e. HeLa cells) although containing an endogenous source of MN protein, did not bind well to the MN protein "dots". Applicant additionally argues that the Zavada *et al* (1997) taught that amount of protein did not correlate to the degree of adhesion. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Specifically, the motivation for one of skill in the art to use human cells in place of the mouse cells (i.e. NIH 3T3 cells) resides in the fact that most experimentation in vitro is to aimed at providing an in vivo result in humans. The use of cell types to more adequate test or experiment is simply an optimization technique that would be considered obvious. Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

Therefore, the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1643
August 29, 2005

SHEELA HUFF
PRIMARY EXAMINER